



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/542,880

09/29/2005

Yasuyuki Kitayama

441P095

8386

42754 7590  
Nields & Lemack  
176 E. Main Street  
Suite #5  
Westboro, MA 01581

05/05/2008

EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,880	<b>Applicant(s)</b> KITAYAMA ET AL.	
	<b>Examiner</b> YONG CHU	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

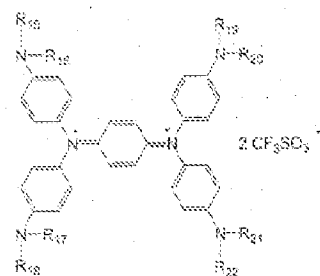
A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/2008 has been entered. Upon entering the submission, claim 8 is currently pending in the instant application.

### *Response to RCE Submission*

#### Remarks or Arguments on rejection of claim 8 under 35 U.S.C. §103(a)

Applicants' arguments on the rejection of claim 8 under 35 U.S.C. §103(a) as being unpatentable over Santo et al., JP 2000-211239 has been considered, but are not persuasive to overcome the rejection.

The instant claim 8 relates to a near infrared absorbing compound salt of



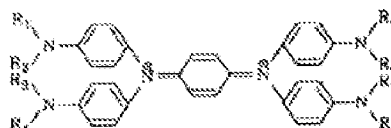
Formula (6)

wherein R<sub>15</sub> to R<sub>22</sub> independently represent a straight-chain or branched butyl or pentyl group.

This compound has two parts, 1) an organic aromatic cation, which contributes to near infrared

Art Unit: 1626

absorption, and 2) an anion counter-ion,  $\text{CF}_3\text{SO}_3^-$ . As cited in the previous Office action, Santo et al, JP 2000-211239 ("Santo") as being recognized by Applicants at page 4 under Remarks shows five compounds of formulae [II]-4, [II]-16, [II]-17, [II]-19



and [II]-25, which have the core structure with  $\mathbf{R}_1\text{-}\mathbf{R}_8$  as branched or straight chain butyl or pentyl groups as required by the instant claim 8, and anions of  $\text{SbF}_6$ ,  $\text{ClO}_4$  and  $\text{NO}_3$ , which is not required by the instant claim 8. In another word, the only difference between the Santo compounds [II]-4 as an example and the instantly claimed compound is the anion of  $\text{Br}^-$  for Santo compound, and  $\text{CF}_3\text{SO}_3^-$  for the instantly claimed compound of claim 8. As being acknowledged by the Applicants,  $\text{CF}_3\text{SO}_3^-$  anion is one of the 36 different possible anions disclosed by Santo at paragraph [0027] as the organic salts. Santo prior art does not leading away from the claimed compounds, because they can be used as a near infrared absorbing compound due to the conjugate aromatic organic cation. The Examiner would like to draw Applicants' attention to the most recent Court holding on *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007), which is a court decision after the Supreme Court *KSR International Co. v. Teleflex Inc.*, 550 U.S., 82 USPQ2d 1385, 1395-97 (2007) decision. The claimed invention in *Pfizer, Inc. v. Apotex, Inc.*, was directed to the amlodipine besylate drug product, which is commercially sold in tablet form in the United States under the trademark Norvasc®. At the time of the invention, amlodipine was known as was the use of besylate anions. Amlodipine was known to have the same therapeutic properties as were being claimed for the amlodipine besylate

Art Unit: 1626

but Pfizer discovered that the besylate form had better manufacturing properties (e.g., reduced “stickiness”). Pfizer argued that the results of forming amlodipine besylate would have been unpredictable and therefore nonobvious. The Court rejected the notion that unpredictability could be equated with nonobviousness here, because there were only a finite number (53) of pharmaceutically acceptable salts to be tested for improved properties. The Court found that one of ordinary skill in the art having problems with the machinability of amlodipine would have looked to forming a salt of the compound and would have been able to narrow the group of potential salt-formers to a group of 53 anions known to form pharmaceutically acceptable salts, which would be an acceptable number to form “a reasonable expectation of success.” Also see MPEP§2143 under (E) “Obvious To Try”. For the instant application, there are only 36 possible anions to try, which is smaller number in comparison with the number in *Pfizer, Inc. v. Apotex, Inc.* case, which is 53 anions to be tested for improved properties. Therefore, the instant rejection over claim 8 is clearly supported by the most recent Court decision. In view of the Court decision, the Toriniwa Declaration filed under Rule 37CFR§1.132 on 02/14/2008 is not sufficient to overcome the instant rejection as nonobviousness results. Accordingly, the rejection of claim 8 under 35 U.S.C. §103(a) is maintained.

### **Conclusion**

No claim is allowed.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./  
Patent Examiner  
Art Unit 1626

Application/Control Number: 10/542,880  
Art Unit: 1626

Page 6